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| SERIAL NUMBER | FILING DATE | FIRST NAMED APPLICANT | | ATTORNEY DOCKET NO. |
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18N1/0529

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| SIDBERRY | AMNER |
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| ART UNIT | PAPER NUMBER |
| 1802 | 47 |
| TE MAILED: | 05/29/96 |

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

| THE PERIOD FOR RESPONS | SE: | | | | | |
|--|--|---|--|--|--|--|
| a) is extended to run | or continues to run | from the date of the final rejection | | | | |
| b) expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection. | | | | | | |
| The date on which the res | ponse, the petition, and the fee have been he period of extension and the corresponding | FR 1.136(a), the proposed response and the appropriate fee. filed is the date of the response and also the date for the g amount of the fee. Any extension fee pursuant to 37 CFR tutory period for response or as set forth in b) above. | | | | |
| Appellant's Brief is due in acc | ordance with 37 CFR 1.192(a). | | | | | |
| Applicant's response to the fin to place the application in con | al rejection, filed 472990 has b dition for allowance: | een considered with the following effect, but it is not deemed | | | | |
| 1. The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because: | | | | | | |
| a. There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented. | | | | | | |
| b. They raise new issues that would require further consideration and/or search. (See Note). | | | | | | |
| c. They raise the issue of new matter. (See Note). | | | | | | |
| They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal. | | | | | | |
| e. They present additi | ional claims without cancelling a correspond | ing number of finally rejected claims. | | | | |
| | (= = = === o.u | = 1 | | | | |
| NOTE: | SEE ATTACH | <u>C</u> 9 | | | | |
| | | | | | | |
| | | | | | | |
| the non-allowable claims. | | lowed if submitted in a separately filed amendment cancelling | | | | |
| Upon the filing an appeal, be as follows: | the proposed amendment will be enter . | ed Will not be entered and the status of the claims will | | | | |
| Claims allowed: | VONE | | | | | |
| Claims objected to: | NONE | | | | | |
| Claims rejected: | 1,67-65 | | | | | |
| However; | | | | | | |
| Applicant's response | has overcome the following rejection(s): | | | | | |
| 4. The affidavit, exhibit or re | quest for reconsideration has been consider | red but does not overcome the rejection because | | | | |
| | | | | | | |
| The affidavit or exhibit will presented. | not be considered because applicant has no | ot shown good and sufficent reasons why it was not earlier | | | | |
| ☐ The proposed drawing correcti | on has has not been approved b | y the examiner. | | | | |
| Other | | HHWELLSIDBERRY PRIMARY EXAMINER GROUP 1800 | | | | |

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Examiner acknowledges the response under 37 CFR 1.116.

The amendment will not be entered because, it does not place the application is condition for appeal by simplifying the issues. The use of the term would incur a rejection under 35 USC 112, 1st and 2nd paragraph as being vague and indefinite, as it unclear what Applicant intends.

The amendment to the claims, raises issues which were raised previously. The use of induction implies that no antibody is present, and the use of enhance suggests that antibody is present and further administration of the antigen is required to "enhance" that which is present.

The use of this term further appears to have no basis in the specification as no host was immunized with the UTTA, and then given the UTTA antigen to show enhanced antibody.

The Examiner has considered the further submitted declarations.

The declaration of Dr. Gupta is unexecuted.

The declaration of Dr. has been considered.

Dr. Gupta indicates that P7A5 was directed to the "same" antigen as the other antibodies in the Paulie reference.

The Paulie et al reference cites a 92K; a 190K and 170K. (see at least the Summary) The statement that "antibody P7A5 is directed to the same antigen as the other antibodies in the Paulie reference" is not sufficient clarification.

Dr. Gupta indicates that a "confirming" letter "from Dr. Paulie is attached" However, the corroborating letter of Dr. Paulie referenced by Dr. Gupta is not attached, and therefore cannot be considered.

Regarding the declaration of Dr. Reisfeld. Dr. Reisfeld maintains that the abstract is noneabling, because it "lacks the information necessary to accomplish" "the isolation and purification of UTAA".

The abstract indicates that urine samples were fractionated by dye ligand and gel filtration chromatography, DEAE anion exchange

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or 4.5% polyethylene glycol precipitation. UTAA in the IgG and IgM fractions was recovered by gel filtration chromatograph. This material was separated into four bands by SDS-PAGE, two which, 142 kd and 111 kd. The antigen is at least substantially pure, as of the claims.

Page 33 of the specification indicates "a variety of chromatographic and affinity absorption techniques were employed to isolate and characterize UTAA from positive serum".

The claims recite "substantially pure". The disclosure of Euhus et al would allow the person of skill in the art to obtain a UTTA antigen within the scope of the claims.

The previously set forth rejections of Papers No. 41:

- (1) The rejection of claims 16 and 62 under 35 U.S.C. § 102(b) as being anticipated by Real et al is maintained for reasons of record.
- (2) The rejection of claims 62-64 rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Paulie et al or Euhus et al is maintained for reasons of record.
- 20 (3) The objection to the specification and the rejection of claims 19 and 65 under 35 U.S.C. § 112, first paragraph, regarding the issue of enhancing the production of antibodies is maintained for reasons of record.
- (4) The objection to the specification and the rejection of 25 claims 62 and 65 under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure is maintained for reasons of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. Sidberry whose telephone number is (703) 308-0170.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

HAZEY HYSIDBERRY PRIMARY EXAMINER GROUP 1800

Sidberry/hfs May 29, 1996